IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

Harald BREIVIK et al.

Application No.: 08/660,331

Patent No.: 5,698,594

Filed: June 4, 1996

Issued: December 16, 1997

For: FATTY ACID COMPOSITION

MAIL STOP: PATENT EXTENSION

Rec'd 6/20/05

APPLICATION FOR EXTENSION OF PATENT TERM PURSUANT TO 35 U.S.C. § 156

MAIL STOP: PATENT EXTENSION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

In accordance with the provisions of 35 U.S.C. § 156 and 37 C.F.R. § 1.701 *et seq.*, the owner of record of U.S. Patent No. 5,698,594 requests that the term of this patent be extended by **1,413 days**, to expire on **June 17, 2013**.

The application (U.S. Application No. 08/660,331), which issued as U.S. Patent No. 5,698,594, was filed on **June 4, 1996** and issued on **December 16, 1997** for "Fatty Acid Composition," listing Harald Breivik, Bernt Börretzen, Knut H. Dahl, Hans E. Krokan, and Kaare H. Bönaa ("Breivik et al.") as inventors. The term of U.S. Patent No. 5,698,594 will expire, unless extended, on **August 4, 2009** (*i.e.*, 20 years from the date on which the application for the patent claims priority, *i.e.*, 20 years from August 4, 1989). The above-referenced patent is a divisional application of U.S. Application No. 08/471,200, filed June 6, 1995 (now U.S. Patent No. 5,656,667), which is a continuation of U.S. Application No.

2005E-0247

APP 1

07/902,500, filed June 23, 1992 (now U.S. Patent No. 5,502,077), which is a continuation of U.S. Application No. 07/389,902, filed August 4, 1989, now abandoned.

Pronova Biocare AS, a Norwegian corporation, is the assignee of the entire right, title, and interest in U.S. Patent No. 5,698,594, granted to Breivik et al. on December 16, 1997 for "Fatty Acid Composition," by virtue of an assignment from the inventors to Norsk Hydro a.s, of Bygdøy Allé 2, 0257 Oslo 2, Norway, August 4, 1989 at Reel 005111 and Frame 0097 for the great grandparent application (*i.e.,* U.S. Application No. 07/389,077) and an assignment from Norsk Hydro a.s, to Pronova Biocare AS, submitted to the U.S. Patent and Trademark Office on September 22, 2004 for recordation. (APPENDICES E and F respectively).

The marketing agent is Ross Products Division of Abbott Laboratories ("Ross Products Division"). A licensing agreement between Abbott Laboratories and Pronova Biocare exists. Under this agreement, Ross Products Division sought and obtained FDA regulatory approval for NDA application 21-654 for OMACOR® Capsules. Evidence of the agreement between the marketing applicant and Pronova Biocare will be furnished upon request, if required.

The undersigned representative submits this application for extension of the patent term of U.S. Patent No. 5,698,594 by providing the following information in accordance with 35 U.S.C. § 156 and 37 C.F.R. § 1.710 *et seq.*, and follows the numerical format set forth in 37 C.F.R. § 1.740(a)(1)-(16). The undersigned attorney has power in this case to act on behalf of Pronova Biocare AS as shown in the Power of Attorney (APPENDIX G).

The following attachments accompany the Application for Patent Term Extension:

Appendix A	Copy of product information about OMACOR® Capsules
Appendix B	Copy of approval letter from the FDA for OMACOR® Capsules
Appendix C	Copy of U.S. Patent No. 5,698,594 and Copy of Certificate of Correction

Appendix D	Copies of Maintenance Fee Statements for U.S. Patent No. 5,698,594
Appendix E	Copy of recorded assignment documents for U.S. Patent No. U.S. Application No. 07/389,902
Appendix F	Copy of Request for Recordation and Copy of Assignment submitted to the U.S. Patent and Trademark Office on September 22, 2004 listing U.S.S.N. 08/660,331, now U.S. Patent No. 5,698,594, assigning the patent from Norsk Hydro a.s to Pronova Biocare AS
Appendix G	Power of Attorney

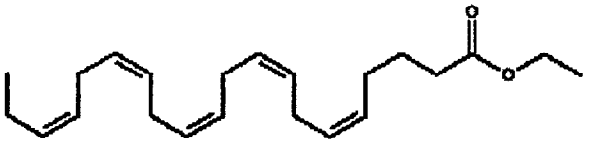
I. 37 C.F.R. § 1.710 (a)(1) TO (a)(15)

(1) IDENTIFICATION OF PRODUCT

The product subject to regulatory review is OMACOR® Capsules (trade name). Product information regarding OMACOR® Capsules is found in APPENDIX A.

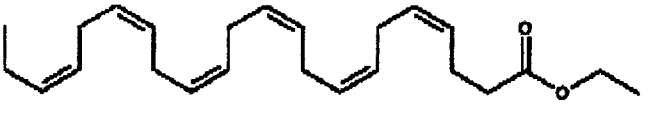
An OMACOR® Capsule contains a lipid-regulating agent and is supplied as a liquid-filled gel capsule for oral administration. OMACOR® Capsules contain 1 gram omega-3-acid ethyl ester liquid concentrate consisting of at least 900 mg omega-3-acid ethyl ester. Each capsule provides approximately 465 mg Eicosapentaenoic acid (EPA) ethyl ester and approximately 375 mg Docosahexaenoic acid (DHA) ethyl ester.

The structural formula of EPA ethyl ester is:



The empirical formula of EPA ethyl ester is $C_{22}H_{34}O_2$, and the molecular weight of EPA ethyl ester is 330.51.

The structural formula of DHA ethyl ester is:



The empirical formula of DHA ethyl ester is $C_{24}H_{36}O_2$, and the molecular weight of DHA ethyl ester is 356.55.

OMACOR® Capsules also contain as inactive ingredients: 4 mg α-tocopherol (in a carrier of partially hydrogenated vegetable oils including soybean oil), and gelatin, glycerol, and purified water (components of the capsule shell). The recommended daily dose is 4 g per day, administered as a single dose or administered twice daily (as 2 capsules of 2 gram each).

OMACOR® Capsules reduce very high (> 500 mg/dl) triglyceride (TG) levels in adult patients. Omega-3 polyunsaturated fatty acids have an effect on hypertension and serum cholesterol.

(2) IDENTIFICATION OF FEDERAL STATUTE/PROVISION OF LAW

OMACOR® Capsules are subject to regulatory review under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355), as a human drug.

(3) **DATE ON WHICH PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR SALE**

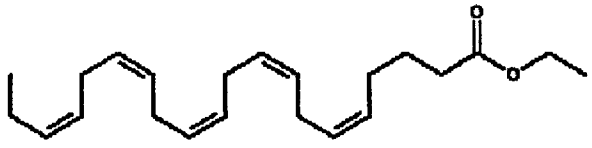
OMACOR® Capsules received permission for commercial marketing under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355), on **November 10, 2004**. A copy of the approval letter is attached as APPENDIX B.

(4) IDENTIFICATION OF EACH ACTIVE INGREDIENT

37 C.F.R. § 1.740(a)(4) requires that in the case of a drug product "an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Public Health Service Act, or the Virus Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved."

OMACOR® Capsules are a lipid-regulating composition. An OMACOR® Capsule is supplied as a liquid-filled gel capsule for oral administration. An OMACOR® Capsule contains 1 gram of omega-3-acid ethyl ester liquid concentrate consisting of at least 900 mg omega-3-acid ethyl ester. Each capsule provides approximately 465 mg Eicosapentaenoic acid (EPA) ethyl ester and approximately 375 mg Docosahexaenoic acid (DHA) ethyl ester.

The structural formula of EPA ethyl ester is:



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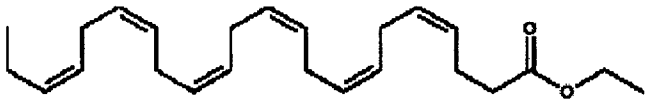

The empirical formula of DHA ethyl ester is $C_{24}H_{36}O_2$, and the molecular weight of DHA ethyl ester is 356.55.

OMACOR® Capsules also contain as inactive ingredients: 4 mg α-tocopherol (in a carrier of partially hydrogenated vegetable oils including soybean oil), and gelatin, glycerol, and purified water (components of the capsule shell). The recommended daily dose is 4 g per day, administered as a single dose or administered twice daily (as 2 capsules of 2 gram each).

OMACOR® Capsules reduce very high (> 500 mg/dl) triglyceride (TG) levels in adult patients. Omega-3 polyunsaturated fatty acids have an effect on hypertension and serum cholesterol.

The active ingredients have not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Public Health Service Act, or the Virus Serum-Toxin Act.

(5) TIME PERIOD FOR SUBMITTING APPLICATION

This application is submitted within the sixty-day period permitted for submission pursuant to § 1.720(f). Specifically, this application is being submitted within the sixty-day period "beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred."

OMACOR® Capsules received permission for commercial marketing under the Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) on **November 10, 2004**. A copy of the approval letter is attached in APPENDIX B. Sixty days from November 10, 2004 is January 9, 2005. However, as January 9, 2005 falls on a Sunday, according to 37 C.F.R. § 1.7, the deadline is extended to Monday, January 10, 2005.

Thus, the last day on which this application could be submitted is **January 10, 2005.**

(6) IDENTIFICATION OF PATENT

The patent for which patent term extension is being sought is U.S. Patent No. 5,698,594, which was filed on June 4, 1996 and issued on December 16, 1997 for "Fatty Acid Composition," to Harald Breivik, Bernt Börretzen, Knut H. Dahl, Hans E. Krokan, and Kaare H. Bönaa, the listed inventors. This patent was filed as U.S. Application No. 08/660,331, which is a divisional of U.S. Application No. 08/471,200, filed June 6, 1995 (now U.S. Patent No. 5,656,667), which is a continuation of U.S. Application No. 07/902,500, filed June 23, 1992 (now U.S. Patent No. 5,502,077), which is a continuation of U.S. Application No. 07/389,902, filed August 4, 1989, now abandoned.

The term of U.S. Patent No. 5,698,594 will expire, unless extended, on **August 4, 2009** (*i.e.*, twenty years from the filing date of the first application to which the patent claims priority, August 4, 1989).

(7) COPY OF PATENT

A copy of U.S. Patent No. 5,698,594 is attached as APPENDIX C.

(8) OTHER PATENT DOCUMENTS

A Certificate of Correction regarding U.S. Patent No. 5,698,594 is enclosed in APPENDIX C. The records of the undersigned do not indicate that any other statutory disclaimer, or reexamination was issued in U.S. Patent No. 5,698,594.

The four-year and eight-year maintenance fees have been paid. A copy of the maintenance fee statements (from the U.S. Patent and Trademark Office Website) verifying the payment is attached as APPENDIX D.

(9) CLAIMS COVERING THE PRODUCT

Some of the methods of use claims of U.S. Patent No. 5,698,594 cover the approved product, OMACOR® Capsules.

As required, Applicant provides a showing of at least one applicable method of use claim and the manner in which the claim reads on the approved product. Claim 12 is a method of use claim that reads on the approved product as noted below.

Claims of U.S.P.N. 5,698,594	OMACOR® Capsules
12. A method for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases, which comprises administering to a patient a mixed-fatty acids composition in which a) at least 80% by weight of the composition is comprised of omega-3 fatty acids, b) at least 80% by weight of the total fatty acid content of the composition is comprised of a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1, c) at least 1% by weight of the total fatty acid content of the composition is comprised of (all-Z omega-3)-6,9,12,15,18-heneicosapentanoic acid, and d) the fatty acids are in admixture with a pharmaceutically acceptable carrier.	OMACOR® Capsules have been approved for the indication of treating hypertriglyceridemia ("HTG"). HTG is a risk factor for cardiac disease. An OMACOR® Capsule contains approximately 465 mg EPA and approximately 375 mg DHA in a capsule of 1,000 mg. The combination of EPA and DHA (omega-3 fatty acids) thus gives approximately 840 mg, *i.e.*, approximately 84% by weight, which fulfills the criteria of "at least 80% by weight" of omega-3 fatty acids. Approximately 465 mg EPA and approximately 375 mg DHA is present in an OMACOR® Capsule, *i.e.*, they are present in a weight ratio of 1.24:1, which fulfills the criteria of "in a weight ratio of EPA:DHA of from 1:2 to 2:1." Heneicosapentanoic acid is present in an amount of approximately 2% by weight of fatty acids in OMACOR® Capsules. Carrier of OMACOR® Capsule is partially hydrogenated vegetable oils including soybean oil. *See* APPENDIX A.

Independent Claim 13 is also a method of use claim that reads on the approved product. Claims 14-20 depend either directly or indirectly from Claim 13 and also read on the approved product.

With respect to Claims 21 and 22, which depend indirectly on Claim 13 and respectively relate to the salt form or free acid form of the fatty acids, Applicant believes these claims may also read upon the approved product. For instance, salt forms are included under the definition of a "product" under 35 U.S.C. § 156(f). *See Pfizer Inc. v. Dr. Reddy Labs. Ltd.,* 359 F.3d 1361, 1364-66, 69 U.S. P.Q.2d 2016, 2018-2019 (Fed. Cir. 2004). In the *Pfizer* case, the Federal Circuit concluded that the statue makes clear that the drug product means the active ingredient, which includes any salt or ester of the active ingredient. *Id.*

(10) RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. § 156(g)

The relevant dates and information pursuant to 35 U.S.C. § 156(g), and 37 C.F.R. § 1.740(a)(10)(i), to enable the Secretary of Health and Human Services to determine the applicable regulatory review period for a patent claiming a human drug are as follows:

(a) The effective date of the investigational new drug (IND) application is **August 15, 1994**. The IND number is **IND 45,998**. The IND application was submitted by Pronova Biocare AS.

(b) The new drug application (NDA) was initially submitted on **January 12, 2004**. The application number was **NDA 21-654**.

(c) The NDA was approved **November 10, 2004**. *See* APPENDIX B.

(11) BRIEF DESCRIPTION OF THE SIGNIFICANT ACTIVITIES

The following is a brief description of the significant activities undertaken by the Applicant and the marketing applicant during the applicable regulatory review period with respect to OMACOR® Capsules and the significant dates applicable to such activities.

Date	To[1]	From	Type	Summary
August 15, 1994[1]	FDA	Pronova	Submission	IND application regarding HTG filed, IND 45,998.
October 19, 1994	Pronova	Consultant[3]	Facsimile	Report concerning FDA contact; protocol amendment to alter sTG levels after dietary intervention portion of trial.
November 20, 1995	FDA	Pronova	Annual Progress Report	Annual progress report that covers the period from September 12, 1994 to September 12, 1995.
December 18, 1995	Pronova	Consultant	Report	Call from and to FDA's Dr. Sheen. Copy of FDA contact report.
February 23, 1996	Pronova	FDA	Letter	FDA requires more information regarding toxicity studies, including rat and mouse carcinogenicity studies.
March 14, 1996			Meeting	Pre-NDA meeting, Metabolic & Endocrine div. (FDA and Pronova).
April 5, 1996	Pronova	Consultant	Minutes	Minutes regarding the Pre-NDA meeting, Metabolic & Endocrine div.
October 18, 1996	Pronova	FDA	Minutes	Additional minutes regarding the Pre-NDA meeting, Metabolic & Endocrine div.
November 24, 1996	Pronova	Consultant	Facsimile	Draft annual report for triglyceride IND 45,998. Covers the period from August 12, 1995 to August 31, 1996.
January 5, 1997	Pronova	Consultant	Facsimile	Concerning Pronova's facsimiles of the 12th and 18th of December 1996; FDA toxicity questions.

Date	To[1]	From	Type	Summary
January 27, 1997	Pronova	FDA	Facsimile	Response to questions from FDA regarding the toxicology review (rat and mouse carcinogenicity studies) on OMACOR® Capsules.
February 14, 1997	Pronova	Consultant	Facsimile	Toxicity diskettes (FDA wants another copy of the tox diskette), tox information.
February 20, 1997	Pronova	Covance[2]	Letter	Oncogenicity studies in rats and mice. Additional copies of the FDA diskettes.
March 4, 1997	Pronova	FDA	Facsimile	Response to questions from FDA regarding the toxicology review (rat and mouse tumorogenicity studies) on OMACOR® Capsules.
August 7, 1998	Pronova	Consultant	E-mail	Confirmation of meeting at Pronova and agenda regarding toxicology studies and CMC.
October 17, 2000	Covance	Pronova	Facsimile	Data regarding oncogenicity studies are sent.
December 12, 2000	Pronova	Covance	Facsimile	Data regarding oncogenicity studies are acknowledged.
October 31, 2001			Meeting	Pre-NDA meeting, Metabolic & Endocrine div.
April 19, 2002	FDA	Ross	Letter	Submissions of review regarding published literature on the effects of omega-3 fatty acid treatment on cardiovascular clinical outcomes.
June 13, 2002			Minutes	Teleconference, Metabolic & Endocrine Division.
July 30, 2003	Ross	FDA	Telephone call	Ross and FDA discusses issues regarding filing of new drug application.
August 13, 2003	FDA	Ross	Facsimile	Ross requests a conference call with the reviewing Medical Officer, Chemistry Reviewer, and Biometrics Reviewer to discuss issues pertaining to NDA 21-654. Additional information regarding CMC/stability of batches is attached.

Date	To[1]	From	Type	Summary
September 10, 2003	Ross	FDA		Amendments which were requested in teleconference regarding additional information regarding OMACOR® Capsules are attached.
October 20, 2003			Minutes	Teleconference, Metabolic & Endocrine Division.
January 9, 2004	FDA	Ross	Submission	NDA 21-654 is filed with the Metabolic & Endocrine Division.
January 12, 2004	FDA		Receipt of document	FDA receives NDA 21-654.
January 20, 2004	FDA	Ross	Submission	
March 25, 2004	Ross	FDA	Letter	Acknowledgement from FDA that the NDA application was sufficiently complete to permit a substantive review.
April 2, 2004	FDA	Ross	Submission	
May 10, 2004	FDA	Ross	Submission	
May 12, 2004	FDA	Ross	Submission	
May 24, 2004	FDA	Ross	Submission	
May 28, 2004	FDA	Ross	Submission	Certificate of analysis.
June 2, 2004	FDA	Ross	Submission	
July 1, 2004	FDA	Ross	Submission	
July 20, 2004	FDA	Ross	Submission	
August 17, 2004	FDA	Ross	Submission	
September 2, 2004	FDA	Ross	Submission	
September 3, 2004	FDA	Ross	Submission	
September 8, 2004	FDA	Ross	Submission	
September 10, 2004	FDA	Ross	Submission	
September 14, 2004	FDA	Ross	Submission	
September 17, 2004	FDA	Ross	Submission	
September 21, 2004	FDA	Ross	Submission	
September 24, 2004	FDA	Ross	Submission	
September 29, 2004	FDA	Ross	Submission	
October 5, 2004	FDA	Ross	Submission	
October 18, 2004	FDA	Ross	Submission	
October 21, 2004	FDA	Ross	Submission	
October 22, 2004	FDA	Ross	Submission	
October 28, 2004	FDA	Ross	Submission	
October 29, 2004	FDA	Ross	Submission	
November 1, 2004	FDA	Ross	Submission	
November 8, 2004	FDA	Ross	Submission	
November 9, 2004	FDA	Ross	Submission	

Date	To[1]	From	Type	Summary
November 10, 2004	Ross/ Pronova	FDA	Letter	FDA approves NDA 21-654.
November 11, 2004	Ross/ Pronova		Letter	Ross/Pronova receives FDA approval of NDA 21-654.

[1] The IND application (IND 45,998) was submitted by Pronova Biocare AS on August 15, 1994. In accordance with a license agreement between Pronova Biocare AS (licensor) and Ross Products Division (licensee), Ross Products Division filed an NDA application with the FDA on January 12, 2004. The NDA application was approved November 10, 2004.

[2] Covance has performed and reported several studies on animal toxicology of OMACOR® Capsules on behalf of Pronova Biocare AS.

[3] Consultant Ronald G. Leonardi (President, R&R Registrations for Pronova Biocare AS).

(12) ELIGIBILITY FOR EXTENSION OF PATENT TERM

U.S. Patent No. 5,698,594 is believed to be eligible for the requested extension of patent term, and the extension is **1,413 days**.

The length of the extension of the term of U.S. Patent No. 5,698,594 of **1,413 days** is based upon 37 C.F.R. § 1.775, which states that the term of the patent for a human drug will be extended by the length of the regulatory review period for the product as determined by the Secretary of Human Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(l) through (d)(6) of this section.

12.1 37 C.F.R. § 1.775(c)

First, the length of the regulatory review period for a human drug will be determined by the Secretary of Human Health and Human Services. Under 35 U.S.C. § 156(g)(3)(B), it is the sum of:

(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 of the Federal Food, Drug and Cosmetic Act became effective for the approved product and ending on the date an application was initially submitted for such product under those sections; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved product under section 505 of the Federal Food, Drug and Cosmetic Act and ending on the date such application was approved under such section.

12.2 37 C.F.R. § 1.775(c)(1)

With respect to 37 C.F.R. § 1.775(c)(1), the date a clinical investigation started was **August 15, 1994**. The date an application was initially submitted with respect to section 505 of the Federal Food, Drug and Cosmetic Act was **January 12, 2004**.

Thus, the "number of days in the period beginning on the date an exemption under subsection (i) of section 505 of the Federal Food, Drug and Cosmetic Act became effective for the approved product and ending on the date an application was initially submitted for such product under those sections" is the number of days between **August 15, 1994** and **January 12, 2004**, which is **3,438 days** (*i.e.*, 9 years and 152 days).

12.3 37 C.F.R. § 1.775(c)(2)

With respect to 37 C.F.R. § 1.775(c)(2), the date the NDA application was initially submitted with respect to section 505 of the Federal Food, Drug and Cosmetic Act was **January 12, 2004**. The date this NDA application was approved under such act was **November 10, 2004**.

Thus, the "number of days in the period beginning on the date the application was initially submitted for the approved product under section 505 of the Federal Food, Drug and Cosmetic Act and ending on the date such application was approved under such section" is the number of days between **January 12, 2004** and **November 10, 2004**, which is **304 days**.

Thus, the sum of the periods in (c)(1) and (c)(2) of this paragraph is **3,742 days** (*i.e.*, 10 years and 90 days).

12.4 37 C.F.R. § 1.775(d)

Next, the regulatory review period for the product, as determined by the Secretary of Human Health and Human Services, is reduced as appropriate pursuant paragraphs (d)(1) through (d)(6) of 37 C.F.R. § 1.775(d). At the outset, Applicant notes that 37 C.F.R. § 1.775(d)(6) is not applicable, since US Patent No. 5,698,594 was not "issued before September 24, 1984."

37 C.F.R. § 1.775(d)(1)(5) states:

> The term of the patent as extended for a human drug, antibiotic drug or human biological product will be determined by-
>
> (1) Subtracting the number of days determined by Secretary of Human Health and Human Services the to be in the regulatory review period:
>
> (i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued:
>
> (ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Human Health and Human Services that the applicant did not act with due diligence;
>
> (iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;
>
> (2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;
>
> (3) By adding 14 years to the date of approval of the application under section 351 of the Public Health and Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug and Cosmetic Act;
>
> (4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;
>
> (5) If the original patent was issued after September 24, 1984,
>
> (i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and
>
> (ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

12.5 37 C.F.R. § 1.775(d)(1)

The periods in paragraph (d)(1) are calculated as follows:

(i) The number of days in the period of paragraph (c)(1) which was on and before the date on which the patent issued (*i.e.*, the period from **August 15, 1994** to **December 16, 1997**) is **1,220 days** (*i.e.*, 3 years and 125 days). The

number of days in the period of paragraph (c)(2) of this section which were on and before the date on which the patent issued is **zero (0) days**, because the patent issued prior to the time the NDA application was submitted (the NDA application was submitted January 12, 2004).

(ii) From August 7, 1998 to October 17, 2000, there is no marketing activity. However, as there is no means by which due diligence can be measured, it is believed that the Applicant acted with due diligence during this period. Therefore, **zero (0) days** are subtracted from the regulatory review period under paragraph (c)(1). In Applicant's opinion, the marketing applicant acted with clear due diligence as defined under 35 U.S.C. § 156(d)(2)(B) during the above calculated period of paragraphs (c)(2). Thus, **zero (0) days** are subtracted from the regulatory review period of (c)(2).

(iii) According to the above, "one-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section" would be 3,438 days minus 1,220 days, which is 2,218 days. One half of 2,218 days is **1,109 days** (*i.e.*, 3 years and 14 days).

Thus, the adjusted period for (c)(1) of 1,109 days added to (c)(2) is 1,109 days plus 304 days, *i.e.*, **1,413 days** (*i.e.*, 3 years and 318 days).

12.6 37 C.F.R. § 1.775(d)(2)

The number of days determined in paragraph (d)(1) of this section is **1,413 days**, as described in detail above.

The patent is not subject to any terminal disclaimer. Thus, the original term of the patent is 20 years from the date of priority, *i.e.* **August 4, 2009**.

Thus, adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent is 1,413 days added to August 4, 2009. This would extend the date to **June 17, 2013**.

12.7 37 C.F.R. § 1.775(d)(3)

The date of approval of the application under subsection (b) of section 505 of the Federal Food, Drug and Cosmetic Act was November 10, 2004.

Thus, adding 14 years to the date of approval of the NDA application under section 505 of the Federal Food, Drug and Cosmetic Act would be **November 10, 2018.**

12.8 37 C.F.R. § 1.775(d)(4)

The dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section are June 17, 2013 and November 10, 2018, respectively. Of these two dates, the earlier date is **June 17, 2013**.

12.9 37 C.F.R. § 1.775(d)(5)

(i) The original expiration date of the patent would be August 4, 2009. Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer would result in a date of **August 4, 2014**.

(ii) The dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section are June 17, 2013 and August 4, 2014, respectively. Of these dates, the earlier date is **June 17, 2013.**

(13) DUTY OF DISCLOSURE

Pronova Biocare AS acknowledges a duty to disclose to the Director of the U.S. Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought herein. Pronova acknowledges that multiple applications for patent term extension have been filed (for U.S. Patent Nos. 5,502,007; 5,656,667; and 5,698,594).

(14) FEES

The Director is hereby authorized to charge the amount of $1,120.00 (37 C.F.R. § 1.20(j)(1)) to Deposit Account No. 02-4800 for receiving and acting upon the application for extension.

The Director is hereby also authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

(15) NAME AND ADDRESS FOR CORRESPONDENCE

Please address all inquiries and correspondence relating to this application for patent extension to:

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(16) MULTIPLE COPIES

This application for extension, together with the appended APPENDICES A through G, are being submitted in original form along with three copies. The undersigned hereby certifies that the copies of this application for extension, together with the appended APPENDICES A through G, filed herewith are true and correct copies.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: January 7, 2005

By: _____
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